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Commentary

Patient notification about suspected hospital-associated outbreaks of invasive mold infections: Considerations for public health and hospital personnel

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Abstract

A common type of fungal disease investigation involves hospital-associated clusters of invasive mold infections (IMIs), which typically occur among immunocompromised patients. Responding to IMI clusters can be challenging for public health and hospital personnel for several reasons such as difficulty of confirming the existence of an outbreak, difficulty of determining source. Although many resources exist to guide patient notification about healthcare incidents (eg, bloodborne exposures, disease outbreaks), IMI clusters involve special considerations related to the complex diseases, uncertain exposures, and differential benefits and risks of notification. Early, nuanced communication about hospital-associated IMI clusters is almost always the best course of action to help reduce risks to patients' health and foster trust between patients and hospitals.

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Fungal disease outbreaks can occur in community or healthcare settings. A common type of fungal disease investigation involves hospital-associated clusters of invasive mold infections (IMIs). These infections typically occur among immunocompromised patients, such as those who have recently undergone transplants (eg, organ or bone marrow) or invasive surgeries, and those with other pre-existing conditions such as uncontrolled diabetes, chronic obstructive pulmonary disorder (COPD), or other respiratory viral infections requiring intensive care (eg, influenza, coronavirus disease 2019 [COVID-19]).[1-8] Investigating and responding to IMI clusters can be challenging for public health and hospital personnel. One of the most challenging aspects of these investigations is determining specific methodologies and practices to best notify patients who are at risk of developing an IMI that a cluster or outbreak is under investigation.[3]

Many resources exist to guide healthcare facilities in patient notification of other types of adverse events, particularly those involving bloodborne pathogen exposures,[9-13] and these resources are also relevant to IMI clusters. However, IMI clusters often entail additional considerations, including patient and healthcare provider lack of familiarity with fungal diseases, which can make patient notification more difficult, even for hospitals with experience notifying patients about other types of events. We aimed to address specific considerations for notifying patients about hospital-associated IMI clusters and outbreaks and to present strategies that public health and hospital personnel can use when approaching patient notification.

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Overview of mold and IMIs

Mold is widely prevalent indoors and outdoors and can travel through the air and persist on surfaces. In particular, molds grow well on materials that remain moist for at least 24–48 hours.[14] Molds do not cause health problems for most people, but for some, they can cause health conditions ranging from allergies or asthma to IMIs. IMIs are serious infections that can cause substantial morbidity and mortality.[1,7,15,16] Of the hundreds of thousands of species of molds, only a small number cause most IMIs, primarily *Aspergillus* species (particularly *A. fumigatus*) and mucormycetes, most of the genera *Rhizopus*, *Mucor*, and *Rhizomucor*. IMIs are associated with an estimated 16,000 hospitalizations and $1.4 billion in direct medical costs in the United States each year, as well as mortality rates as high as 50% in persons with immunocompromising conditions.[15,17-19] Mucormycosis (infections caused by mucormycetes) most commonly occur in immunocompromised patients. Invasive aspergillosis (infections caused by *Aspergillus*) also occurs in immunocompromised patients, but cases have also been reported in immunocompetent patients in the intensive care unit (ICU) or following surgery.[20-24] One study reported that ~10% of invasive aspergillosis cases occurred in postsurgical patients.[25]

Overview of IMI clusters and outbreaks

The annual number of IMI clusters and outbreaks in the United States is unknown, primarily because IMIs are usually not reportable to public health in this country through systematic surveillance. In

the United States, only Seattle–King County, Washington, has made IMI cases reportable (starting in February 2020), and aspergillosis is reportable in Louisiana. Therefore, routine baseline data about IMI frequency are often unavailable. Given the absence of public health surveillance for IMIs, most IMI investigations arise when a healthcare facility identifies a cluster of cases that share a common location, population, or time period.

An IMI cluster is a group of 2 or more patients with IMI that may signal an ongoing outbreak but has either not been fully investigated or lacks sufficient data to confirm the existence of an outbreak. Because of the challenges inherent in confirming IMI outbreaks, clusters are important signals that often prompt further investigation. An IMI cluster is considered an IMI outbreak when the number of infections is confirmed to be larger than expected within a defined population (ie, certain high-risk patients) over a specific period (e.g., 6 months), or when 2 or more cases are linked to a common source. An increased incidence over an estimated baseline rate or the presence of IMI in patients who are not considered at highest risk should also prompt evaluation by public health and hospital personnel.[24] In addition, a case of IMI with suspected hospital exposure (e.g., admission >7 or 14 days before presumed IMI onset or one that is associated with surgery) should prompt evaluation. Patient notification should be considered in both clusters and outbreaks because clusters may later be confirmed as outbreaks and early notification is key to helping reducing risk to patient health; here, we refer to them collectively as clusters for simplicity.

Because IMI clusters often involve a small number of patients and mold exposure can occur in many settings, identifying the exposure source is often difficult. Confirmed sources have included construction or demolition sites, water damage, and ventilation system deficiencies.[1,18,26-30] Less common sources include hospital linens, medications, foods, and medical supplies and equipment.[3,31-35] Even if the source cannot be identified, all investigations offer opportunities for healthcare facilities to inspect and remediate possible sources to improve patient safety. When a US healthcare facility identifies an IMI cluster, it should notify its local or state public health department; health departments can contact CDC (fungaloutbreaks@cdc.gov) for additional assistance. Additionally, an industrial hygienist can also be contracted to assist with the investigation in the hospital setting.

Healthcare-associated IMI clusters can attract substantial media attention. Recent examples include a 2014–2015 mucormycosis outbreak in Pennsylvania and a 2018–2019 aspergillosis outbreak in Washington state.[36,37] Media coverage of these events represent one of the few opportunities for the general public to learn that molds can cause infections.

Communicating with the public and the media about IMI clusters can be challenging, particularly because these clusters involve severe infections, can be difficult to confirm, and often involve unclear sources. Communication strategies employed in other contexts, such as breaches in infection control and injection safety,[9,13] can be applied to IMI clusters, though additional considerations are often appropriate. One such factor is that mold may be perceived as associated with visibly unhygienic conditions, even though mold exposures can occur in the absence of visible mold. Additionally, IMI clusters can be particularly challenging to investigate, complicating patient notifications. We briefly summarize these challenges below.

Challenges to identifying healthcare-associated IMI clusters

Several features of IMIs make them particularly challenging to investigate, not least of which is that many infection control staff lack experience dealing with IMI clusters. IMI signs and symptoms are often nonspecific and sometimes insidious at the outset, making it difficult to establish an onset date in many cases. In addition, the incubation period for several IMIs, particularly noncutaneous mucormycosis, is not well defined,[3,38] largely because it is difficult to ascertain an exposure date. For this reason, investigators typically use a wide exposure window (e.g., 14 days or longer) when evaluating exposures as potential sources. Diagnosis of an IMI typically requires invasive specimens for culture or histopathology; adjunctive tests like galactomannan, β-D-glucan, and PCR testing can provide supportive evidence. Given the multiple testing modalities, creating case definitions and performing laboratory-based case finding can be complex. No simple test exists for reliably diagnosing IMI[39,40] because a positive laboratory test can signify infection or colonization, necessitating additional contextual information in many cases. IMIs are among the most common missed diagnoses among ICU patients;[41] delays in diagnosis can increase the severity and mortality of IMIs. Even thorough IMI investigations may fail to identify a source, particularly for small clusters, which have few cases to provide epidemiologic clues.[3] The list of potential mold sources is lengthy, as described above, and mold can be difficult to detect in the environment unless visible contamination is present.

Challenges to environmental sampling during suspected healthcare-associated IMI clusters

Environmental sampling is often seen as the critical step in identifying a source of an IMI outbreak, but its utility is often overestimated. It is best performed using a well-designed sampling plan in combination with a thorough environmental assessment, sometimes under the guidance of an industrial hygienist, to most effectively identify the mold source. Other important considerations include environmental sampling equipment, experience of the person performing the air sampling, and the expertise of the microbiology lab. Conventional microbiologic methods may not always accurately speciate molds, which is important when comparing environmental sampling results with those from patients. Additionally, the diagnostic criteria needed to distinguish invasive infection from colonization are complex, and mycology laboratory capacity for species determination can vary by hospital, often leading to misidentifications in clinical laboratories.[3]

In addition to laboratory challenges, environmental testing results can be difficult to interpret. An environmental sample positive for mold can help identify potential targets for remediation but such a finding cannot be interpreted as indicating a definitive source of transmission in the absence of an epidemiologic link to patients.[3] A negative result is limited in that it indicates that spores were not present at the specific time of sampling using a specific method, but such results cannot be used to rule out the presence of mold because mold may not be consistently present.[3] Furthermore, because environmental conditions can change between time of exposure and when sampling is conducted, a negative test does not exclude previous contamination of the sampled site.

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Considerations for patient notification about IMI clusters and outbreaks

Why notify

Timely patient notification has several benefits. First, it can allow for earlier diagnosis and treatment, which is important given that delayed recognition is associated with poorer IMI outcomes. Second, it can reduce the likelihood of inaccurate messages spreading to patients and the public and improve trust in and credibility of the healthcare organization.[42-45] Conversely, delayed patient notification can allow potentially false information or misperceptions, speculation, or biased messaging to spread, and can have substantial economic, legal, and reputational consequences.[46] For example, a 2014–2015 mucormycosis outbreak in Pennsylvania cost the facility millions of dollars, including two ~$1 million settlements,[37] and a long-term aspergillosis outbreak in Washington led to 6 deaths and the closure of all hospital operating rooms.[47]

Messaging that is more likely to instill trust and credibility often includes language indicating transparency, empathy, respect, expertise, and what is being done to identify and correct the problem.[10-12] Trust and credibility can also allow public health and healthcare and hospital personnel to better persuade affected patients to follow public health authorities' recommendations. For patients and the public, the first source of information can often become the preferred source.[10] Additionally, even if harm to certain patients is unlikely, and public health, and healthcare, and hospital personnel do not have specific actions to recommend, patients have the right to be informed if their healthcare provider or facility failed to meet the expected standards of care.[13,43]

Whom to notify

When an IMI cluster is identified, the underlying medical conditions (e.g., hematologic malignancy, postsurgical, transplant) of the patients involved and other epidemiologic factors (e.g., locations within a hospital) can be used to determine which patient populations should be notified. Ideally, patient notification should be guided by exposure to a suspected source; however, given the challenging nature of detecting the source, determining which patients were exposed can be difficult. When a source is detected, the type of source and patient exposures should guide which patients should be notified. When in doubt, it is preferable to err on the side of broader rather than narrower notification. In most cases, notification strategies should ensure patients who have been infected are notified and counseled promptly.[12,13] Notification of patients who have been exposed (or potentially exposed) should follow as soon as possible, either simultaneously or sequentially.[12] In some circumstances, hospital personnel may decide to prescribe additional or enhanced antifungal prophylaxis specific to the IMI of concern, a complex decision that must weigh the potential risks and benefits, was well as feasibility, since insurers may deny enhanced antifungal therapy given the high cost. Patients receiving this prophylaxis should also be notified.

When to notify

Similarly, regarding the notification timing, earlier is better, even if information is incomplete; some guidance recommends notifying patients within 24 hours of when an outbreak is suspected, although that timeline can be challenging in IMI clusters given the many inherent uncertainties.[12] Still, timely patient notification can encourage patients to seek care early if they have compatible symptoms, potentially reducing delays in diagnosis and treatment,[48,49] as well as misdiagnosis. However, lack of perceived diagnostic benefit should not preclude timely patient notification because other reasons may exist. Healthcare personnel may also be hesitant to notify patients while still gathering preliminary data or before confirming that a cluster exists. Although public health and hospital personnel may have concerns that early patient notification about an IMI cluster might cause unnecessary anxiety or fear, waiting too long can cause even worse fear, loss of trust, or frustration, and can lead to additional infections and deaths.[9,13] Patient notification should be timed so as to allow public health and hospital personnel to effectively manage and support an ongoing investigation, as well as give patients adequate time to seek medical care or further information.[9,12]

Other considerations for patient notification

When notifying patients and staff about an IMI cluster or outbreak, consider sharing the following information:

- Why they are being contacted
- Brief background on mold, how exposures and infections can happen, and symptoms of an infection
- General information about the cluster or outbreak (e.g., what is known and not known)
- What steps are being taken to investigate the cluster, to protect patients, and to prevent similar outbreaks from occurring
- What they should do if they have symptoms of infection, and how testing and treatment costs will be handled, and
- Who patients should contact if they have questions or concerns (e.g., their healthcare provider, a hotline)

This information can be as simple as stating that the healthcare facility has seen a larger number of these infections than expected, that the healthcare facility is working to ensure a safe environment, and that more information may become available as the investigation progresses.[10,12] In some situations, it may also not be clear that the IMIs are associated with healthcare settings, which should be explained to patients. In general, public health personnel can assist healthcare facilities in assessing when and how patient notification should occur during an IMI cluster. Maintaining communication between public health and hospital personnel is key, including in developing overall communications and media strategies and informing others when any group plans to share new information from the investigation.[9,12] Public health personnel should defer to hospital personnel to notify both patients and the public about an IMI outbreak, unless circumstances prevent them from doing so (eg, the facility is closed or lack of cooperation or timeliness).[12] Under these circumstances, public health personnel notify patients.

The importance of plain writing

Whenever possible, messaging about IMI clusters should incorporate plain writing. Plain writing is defined as clear, concise, well-organized messaging appropriate for the subject and the intended audience, that can be understood the first time the audience reads or hears the information.[50] This aspect is especially important for patients and family members with low health literacy, which is common (~40% of US adults).[51-53] Few available data clearly describe how the public specifically understands mold and its associated health risks. Limited research shows that people perceive the risks of mold to their health to be relatively low, but this was specifically in the context of a postdisaster setting.[18] Messaging about IMI clusters to all patients and families should be easy to

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understand, and language and other communication barriers may need to be addressed.[51]

Methods for and examples of using patient notification in IMI outbreaks

Notification methods can include mailed documents, electronic messages, in-person discussions, and telephone calls. Telephone calls or in-person discussion are preferred if the number of patients being notified is relatively small, and telephone calls may be most feasible for patients who have already been discharged from the facility.[9,12,13] Following telephone calls and in-person discussions, written information should be provided to patients so they have easily accessible and accurate documentation to refer back to or share with caregivers and other healthcare providers.

Recently, general guidance for emergency and risk communication strategies for suspected outbreaks have become available and include the CDC Introduction to Patient Notification Toolkit[9] and Crisis and Emergency Risk Communication Manual.[10] The Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial-Resistant Pathogens' (CORHA) Interim Framework for Healthcare-Associated Infection Outbreak Notification also provides guidance for notification in the context of a suspected healthcare-associated infection (HAI) outbreak.[12]

The following scenarios describe fictional examples of patient notification during IMI cluster investigations intended to represent how notification can affect outcomes. They do not reflect actual events.

1. Hypothetical mucormycosis cluster. A hospital identified 6 cases of mucormycosis (3 *Rhizopus* and 3 *Mucor* spp.) among ICU patients receiving mechanical ventilation over the previous 4 months, none of whom were immunosuppressed, apart from in-hospital corticosteroid use. Five had been hospitalized for >2 weeks before suspected mucormycosis onset. For comparison, only 2 cases of mucormycosis had been diagnosed in ICU patients over the previous 3 years. A team at the hospital began to investigate by reviewing patient records and taking air and surface samples for mold spore identification. The air and surface samples identified a relatively low level of mold spores (although no specific guidelines exist for healthcare settings), with few spores suggestive of mucormycetes. The team suspected that the cluster of cases might have reflected increased use of diagnostics to detect mucormycosis; no patient notification was performed.

Over the next 3 months, 5 more cases of mucormycosis were identified in ventilated patients. Environmental sampling was performed again, with similar results. One patient's family contacted a local television news station, which aired a story about deadly mold infections at the hospital, prompting concern from many patients and families. National news coverage followed.

In consultation with the state health department and an industrial hygienist, the hospital performed a thorough environmental assessment and identified a likely source: water-damaged building materials in a wall of the ventilator storage area. Previously unidentified gaps in the room wall, along with unbalanced air flow, allowed dust into the clean storage area. Targeted culture-based air and surface samples identified high levels of mucormycetes, and the area was successfully remediated.

2. Hypothetical aspergillosis cluster. A hospital notified their local health department after identifying three cases of aspergillosis over the previous 3 months in inpatients with hematologic malignancies. Two of these patients had been inpatients for >14 days before the suspected aspergillosis onset date, suggestive of healthcare-acquired infections. On a retrospective review of microbiology and pathology data, 0–1 cases per year had been identified over the past 5 years. Based on the cluster epidemiology and knowledge of high-risk conditions for IMI, healthcare personnel created a list of patients who had been treated for hematologic malignancy at this hospital in the month before the first cluster case. Patients, or family members when appropriate, on this list were notified at in person-visits or by telephone and were provided a letter and fact-sheet that described the cluster, the patients' potential health risks, general information about IMIs, and recommendations for patients and visitors entering the facility. Despite thorough investigation, the source was not identified, but based on an environmental assessment, the hospital made several improvements to the ventilation system, cleaning procedures, and linen storage. The infection control team also instituted new policies for routine assessment of potential mold sources, including meetings with building engineers and maintenance.

Communicating early and proactively about potential healthcare-associated IMI outbreaks is key to helping reduce additional risks to patients' health. Early notification can allow patients to feel more informed about their health status and helps foster trust between patients and healthcare facilities. Successful patient notification relies on close collaboration between healthcare facility personnel, public health, and communication professionals. IMI outbreaks often involve many scientific uncertainties and challenges, especially in identifying the source. More research is needed on how and why healthcare-associated mold outbreaks occur and on IMIs in general. Insight into the general public's knowledge and perceptions about mold as it relates to health is also needed. Establishing regional or nationwide surveillance for IMIs would also help establish the true prevalence of these infections and help identify baseline rates and outbreaks. In summary, despite the challenges associated with identifying and communicating about healthcare-associated mold outbreaks, patient notifications are an important part of the response to IMI outbreaks, allowing patients and providers to make informed care decisions.

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Appendix A. Example Patient Notification Letter

Dear [patient/family member name],

We have recently noted a higher than usual number of infections in patients who have received care at our facility that is caused by a specific kind of fungus. These infections have happened in patients who have had weakened immune systems from a recent bone marrow transplant, chemotherapy for leukemia, or a very low white blood cell count (neutropenia) that lasted for several weeks or more. This type of infection typically does not affect people whose immune systems are healthy. As you may know from conversations with your or your loved one's care team, the risk of infection during treatment for cancer is a great concern due to the weakening of the immune system that often accompanies treatment.

We are contacting you because . . . [why patient was selected to receive letter]. We want to make sure you know how to protect yourself or your loved one from risks from this fungus, which commonly lives in the soil and other places in the environment. Spores from these fungi are common in air. People breathe in these spores every day.

What we are doing to protect patients

To protect our patients who are at risk of infection from fungus, our facility is taking several important precautions. These include conducting a thorough investigation to determine whether these recent infections originated inside the hospital and taking extra steps to make sure the air inside is as clean as possible.

What you can do to protect yourself

At this time, we don't know where the fungus that infected these patients came from. We are currently assessing this issue and want to remind you of the following ways to reduce your risk of infection:

- Try to avoid areas with a lot of dust like construction or excavation sites. If you must be outdoors near these types of sites, wear an N95 mask. These are specialized masks that filter the air that you breathe.
- Avoid activities that involve close contact to soil or dust, such as yard work or gardening. Do not go inside dusty places like barns, sheds or greenhouses, or be in the vicinity of home renovation projects (such as tearing down walls or pulling up carpets), mulching, plowing, or mowing.
- Take preventive antifungal medications if prescribed by your care team.

As always, if you/your loved one notice unexpected symptoms that could be a sign of infection, such as fever or headache that don't go away, new cough, or sinus pain, contact your nurse coordinator to ask whether you/your loved one should be evaluated.

If you have any questions about your risk of infection, please call your nurse coordinator or talk to your healthcare provider at your next appointment. Thank you for trusting us with your care. We will keep you updated on anything we learn.

Your Care Team

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